B	L	A. A.	-
H	only	leave	
Ol/	$\bigcup$	J47	

## SEARCH REQUEST FORM

Access DB#

Scientific and Technical Information Center

JULY -9 2007

	1) -1		70 th 2 11.11	
Requester's Full Name:	Murane Josen	Examin	er # : 1299 D ial Number: 0	atg: DAJULOC
Art Unit: 1619	Phone Number 30 8	<u>-4634</u> Ser	ial Number:	71951,016
Mail Box and Bldg/Room	1 Location: 2000) (CA	Results Form	at Preferred (circle): P	APER PISK E-MAIL
If mor than one search	h is submitted, please p			·************
Include the elected species or utility of the invention. Defin	ment of the search topic, and of structures, keywords, synonyr the any terms that may have a sp of the cover sheet, pertinent cla	ns, acronyms, and repectal meaning. Given	egistry numbers; and com	bine with the concept or
Title of Invention;	ARR.	attachel	sleet	
Lifventors (please provide fu	ill names):	<u> </u>		
Earliest Priority Filing D	ate:	1		
*Far Sequence Searches Only* apprapriate sérial number.	Please include all pertinent infa	rmatian (parent, chil	d, divisianal, or issued pater	nt numbers) along with the
A. J. S. J.	$\Lambda_{\Lambda}$		•	

Please rearch claim 1,2 and 14

NECEIVED JUL -9 2

## **BEST AVAILABLE COPY**

Point of Contact: Barb O'Bryen Technical Information Specialist STIC CM1 6A05 308-4291



	Type of Search	Vendors and cost where applicable
Searcher:	NA Sequence (#)	stn/3
Searcher Phone #:	AA Sequence (#)	Dialog 30
Searcher Location:	Structure (#)	Questel/Orbit
Date Searcher Picked Up:	Bibliographic &	Dr. Liŋk
Date Completed. 7-17-02	Litigation	Lexis/Nexis
Searcher Prep & Review Time: 20	Fulltext'	Sequence Systems
Clerical Prep Time:	Patent Family	WWW/Internet
Online Time: 47	Other	Öther (specify)
PTO-1590 (8-01)		

## WHAT IS CLAIMED IS:

- 1. A method for alleviating or reducing the toxic, nutritional and metabolic disturbances associated with cancer and cancer chemotherapy comprising: administering to a patient a composition comprising an effective amount of riboflavin, an effector of the urea cycle, and the amino acids alanine, glycine, serine, taurine, threonine and valine.
- 2. A method according to claim 1 wherein the effector of the urea cycle is arginine, ornithine or citrulline.
- 3. The method of claim 1 wherein the amino acids are in free form or pharmacologically acceptable salts.
- 4. The method of claim 1, wherein the concentration of riboflavin is about 5 to about 300 mg/L.
- 5. The method of claim 1, wherein the concentration of the effector of the urea cycle is about 2 to about 120 mg/L.
- 6. The method of claim/1, wherein the concentration of alanine is about 1 to about 90 mg/L, the concentration of glycine is about 1 to about 75 mg/L, the concentration of serine is about 1 to about 75 mg/L, the concentration of threonine is about 1 to about 90 mg/L and the concentration of valine is about 1 to about 50 mg/L.
- 7. The method of claim 1, wherein said composition is administered enterally or parenterally.
- 8. The method of claim 1, wherein composition is administered intravenously.

- 9. The method of claim 1, wherein said composition further comprises at least one pharmaceutically-acceptable carrier, diluent, or excipient.
- 10. The method of claim 1 wherein the composition consists of riboflavin, arginine, alanine, glycine, serine, taurine, threonine, valine and a pharmaceutically-acceptable carrier or diluent.
- 11. The method of claim 10, wherein the concentration of riboflavin is about 5 to about 300 mg/L, the concentration of arginine is about 2 to about 120 mg/L, the concentration of alanine is about 1 to about 90 mg/L, the concentration of glycine is about 1 to about 75 mg/L, the concentration of serine is about 1 to about 75 mg/L, the concentration of taurine is about 0.5 to about 30 mg/L, the concentration of threonine is about 1 to about 90 mg/L and the concentration of valine is about 1 to about 50 mg/L.
- 12. The method of claim 1, wherein the composition consists of riboflavin, ornithine, alanine, glycine, serine, taurine, threonine, valine and a pharmaceutically-acceptable carrier or diluent..
- 13. The method of claim 12, wherein the concentration of riboflavin is about 5 to about 300 mg/L, the concentration of ornithine is about 2 to about 120 mg/L, the concentration of alanine is about 1 to about 90 mg/L, the concentration of glycine is about 1 to about 75 mg/L, the concentration of serine is about 1 to about 75 mg/L, the concentration of taurine is about 0.5 to about 30 mg/L, the concentration of threonine is about 1 to about 90 mg/L and the concentration of valine is about 1 to about 50 mg/L.
- 14. A pharmaceutical composition for alleviating or reducing the toxic, nutritional and metabolic disturbances associated with cancer and cancer chemotherapy comprising: an effective amount of riboflavin, an effector of the urea cycle, and the amino acids alanine, glycine, serine, taurine, threonine, and valine.
- 15. The pharmaceutical composition of claim 14, wherein the effector of the urea cycle is selected from arginine, ornithine or citrulline, wherein the effector is in free form or a pharmacologically acceptable salt.

- 16. The pharmaceutical composition of claim 14 wherein the amino acids are in free form or pharmacologically acceptable salts.
- 17. The pharmaceutical composition of claim 14, wherein the concentration of riboflavin is about 5 to about 300 mg/L.
- 18. The pharmaceutical composition of claim 1/4, wherein the concentration of the effector of the urea cycle is about 2 to about 120 mg/L.
- 19. The pharmaceutical composition of claim 14, wherein the concentration of alanine is about 1 to about 90 mg/L, the concentration of glycine is about 1 to about 75 mg/L, the concentration of serine is about 1 to about 75 mg/L, the concentration of taurine is about 0.5 to about 30 mg/L, the concentration of threonine is about 1 to about 90 mg/L and the concentration of valine is about 1 to about 50 mg/L.
- 20. The pharmaceutical composition of claim 14, having a pH of about 6.0 to about 7.0.
- 21. The pharmaceutical composition of claim 14, further comprising at least one pharmaceutically-acceptable carrier, diluent, or excipient.
- 22. The pharmaceutical composition of claim 14, consisting of riboflavin, arginine, alanine, glycine, serine, taurine, threonine, valine and a pharmaceutically-acceptable carrier or diluent.
- 23. The pharmaceutical composition of claim 22, wherein the concentration of riboflavin is about 5 to about 300 mg/L, the concentration of arginine is about 2 to about 120 mg/L, the concentration of alanine is about 1 to about 90 mg/L, the concentration of glycine is about 1 to about 75 mg/L, the concentration of taurine is about 30 mg/L, the concentration of threonine is about 1 to about 90 mg/L and the concentration of value is about 1 to about 50 mg/L.

- 24. The pharmaceutical composition of claim 14, consisting of riboflavin, ornithine, alanine, glycine, serine, taurine, threonine, valine and a pharmaceutically-acceptable carrier or diluent..
- 25. The pharmaceutical composition of claim 24, wherein the concentration of riboflavin is about 5 to about 300 mg/L, the concentration of ornithine is about 2 to about 120 mg/L, the concentration of alanine is about 1 to about 90 mg/L, the concentration of glycine is about 1 to about 75 mg/L, the concentration of serine is about 1 to about 75 mg/L, the concentration of taurine is about 0.5 to about 30 mg/L, the concentration of threonine is about 1 to about 90 mg/L and the concentration of valine is about 1 to about 50 mg/L.
- 26. A method for alleviating or reducing the toxic, nutritional and metabolic disturbances associated with cancer and cancer chemotherapy comprising: administering to a patient a composition comprising an effective amount of riboflavin, an effector of the urea cycle comprising arginine and ornithine, and the amino acids alanine, glycine, serine, threonine and valine.
- 27. The method of claim 26, wherein the composition further comprises 3-phenylacetylamino-2,6-piperidinedione.
- 28. The method of claim 26, wherein the composition consists of 0.01-10 wt % riboflavin, 1-15 wt % arginine, and 1-15 wt % ornithine, 1-15 wt % alanine, 1-15 wt % glycine, 1-15 wt % serine, 1-15 wt % threonine 1-15 wt % valine, and 25-75 wt % 3-phenylacetylamino-2,6-piperidinedione.
- 29. A pharmaceutical composition for alleviating or reducing the toxic, nutritional and metabolic disturbances associated with cancer and cancer chemotherapy comprising: an effective amount of riboflavin, an effector of the urea cycle comprising arginine and ornithine, and the amino acids alanine, glycine, serine, threonine and valine.
- 30. The pharmaceutical composition of claim 29, further comprising 3-phenylacetylamino-2,6-piperidinedione.

31. The pharmaceutical composition of claim 29, consisting of 0.01-10 % riboflavin, 1-15 % arginine, and 1-15 wt % ornithine, 1-15 wt % alanine, 1-15 wt % glycine, 1-15 wt % serine, 1-15 wt % threonine 1-15 wt % valine, and 25-75 wt % 3-phenylacetylamino-2,6-piperidinedione.





## UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
WASHINGTON, D.C. 2023I
WWW.USplo.gov

**CONFIRMATION NO. 9045** 

	TAIN THEN TIME FOR THE STATE	E FTIL BLAIB HTIB I HHTB A I BA
Bib	Data Sheet	

SERIAL NUMBER 09/995,010	11/27/2001 RULE	<b>CLASS</b> 51 <b>4</b>		JNIT 1614		DOCKET NO. 9.0049.NPUS00	
APPLICANTS Stanislaw R	. Burzynski, Houston,	TX;					
** CONTINUING D	)ATA ************	****				·	
** FOREIGN APPL	LICATIONS ********	****					
IF REQUIRED, FC ** 03/18/2002	REIGN FILING LICE	NSE GRANTE	D** SMALL E	ENTITY **		(	
Foreign Pnonty claimed 35 USC 119 (a-d) condit met Verified and Acknowledged	yes ☐ no ions ☐ yes ☐ no Allowance  Examiner's Signature	Met after	STATE OR COUNTRY TX	SHEETS DRAWING	TOTAL CLAIMS 31	INDEPENDENT CLAIMS 4	
ADDRESS HOWREY SIMON 750 Bering Drive Houston ,TX 7705	ARNOLD & WHITE	<u> </u>					
TITLE							
Formulation of ami	ino acids and nboflav	in useful to rec	luce toxic effe	cts of cytotox	kic chemotherap	y	
	FEE <b>S</b> : Authority has been given in Paper No to charge/credit DEPOSIT ACCOUNT No for following:				All Fees		
FILING FEE FI					☐ 1.16 Fees (Filing)		
					1.17 Fees ( Processing Ext. of time )		
576 N				11.—	1.18 Fees (Issue)		
					Other		
				Credit			
			***************************************				